

SOLABS QM10

Retiring a Document

Contents

Introduction	1
Document Statuses in SOLABS QM10:	1
Document Status Tabs – Visual Indication of Status	2
Retiring a Document	3
Locating the Document.....	3
Retiring the Document	3

Introduction

This document provides a summary of the various document statuses in **SOLABS QM10** and covers the process for totally Retiring an existing document, instead of Modifying it to replace it with a newer version.

To retire a document in **SOLABS QM10**, you will need at least **Modify** privileges to the related folder.

A **Retired** status is available as part of the life cycle in the DOCUMENT section. The Document Control Process also includes an option for **Retire** at Step 1 in the workflow. This allows initiators to request the retirement of a document and get Owner-Manager approval before the workflow goes to the Document Coordinator for the process described in this document.

Document Statuses in SOLABS QM10:

The following table describes the various **Document Statuses**, as well as the visual clues that provide information to you about the status of the document you are viewing.

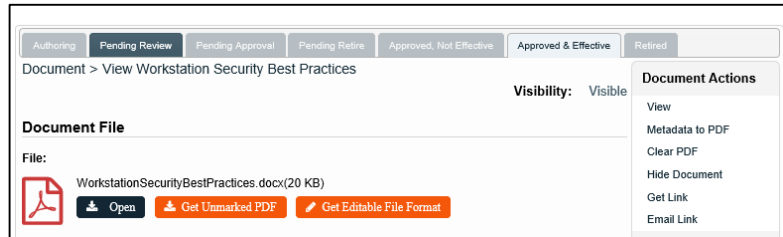
Document Status	Meaning
Authoring	This Document is in the process of being written or revised. At this stage, it does not yet have official Status , and, depending on your configuration, is only available, visible and/or editable to Document Coordinators (and related Roles) and/or the Author .
Pending Review	This Document is in an active Review Cycle and is Awaiting Review from one or more of the assigned Reviewers .
Pending Approval	This Document is in an active Approval Cycle and is Awaiting Approval from one or more of the assigned Approvers .

Pending Retire	This Document is in an active Retire Cycle and is Awaiting Retire Status from one or more of the assigned Retirers .
Approved, Not Effective	The Approval Cycle for this Document is complete. It is now Approved , but has not yet been made Effective . The only remaining steps for this document are for the Document Coordinator to change the status to Effective , or for a pre-determined Effective Date to be reached.
Approved & Effective	This is the current, official version of this Document — it has been put to a status of Effective by a Documentation Coordinator or has reached the pre-determined Effective Date and has automatically been made Effective .
Retired	This Document has been retired from active use and is therefore no longer Effective . It is archived and can be retrieved through the Audit Trail by SOLABS Document Administrators in case it ever needs to be re-activated and/or used partially or wholly in another Document .

Document Status Tabs – Visual Indication of Status

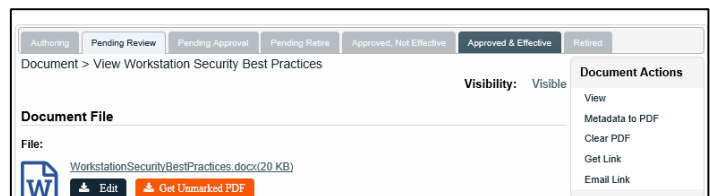
Document life cycle status tabs are visible at the top of a **Document** screen, whether in **View** mode or in **Modify** mode. The light grey tab indicates the status of the version you are currently viewing or working on. A dark grey tab indicates another status of the same document.

In this example, the information for the **Approved & Effective** version of this document is being viewed. The dark grey color of the **Pending Review** tab indicates that another version of this document is in progress and is in an active **Review Cycle**.



You can toggle back and forth between the two active statuses by clicking on the light grey and dark grey tabs.

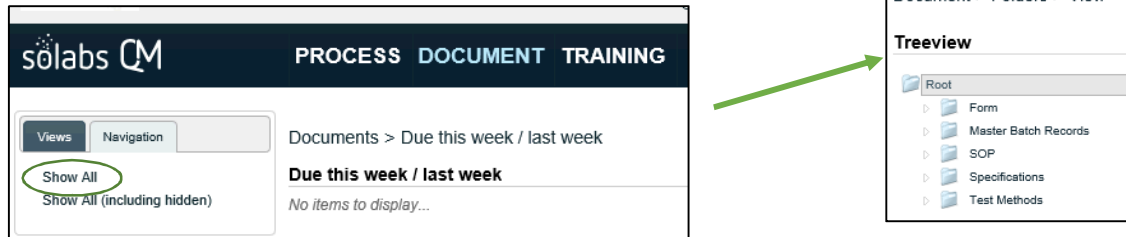
NOTE: The **Approved & Effective** version is in PDF file format while the **Pending Review** version is in Word format – another visual indicator of status.



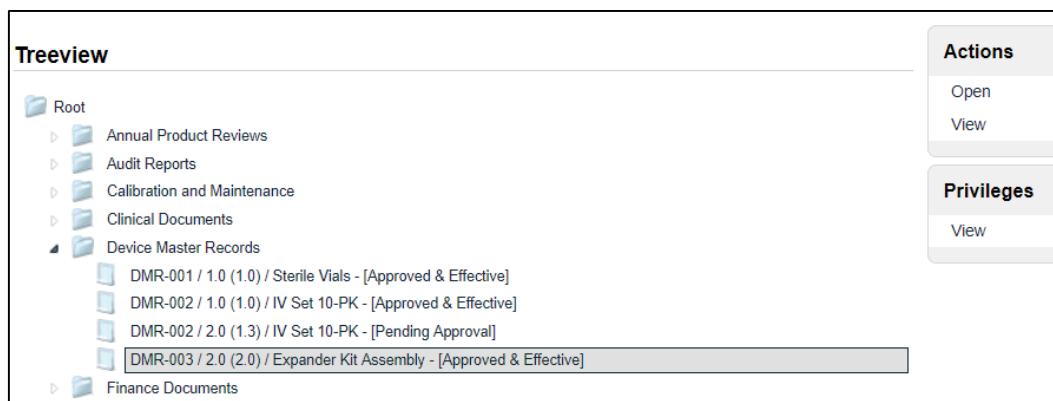
Retiring a Document

Locating the Document

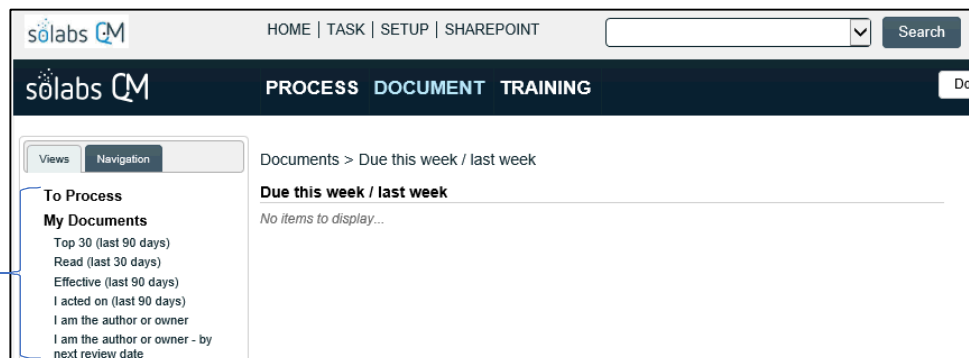
As a user with at least Modify privileges, choose **DOCUMENT** from the main menu at the **SOLABS QM10 Home** page. Click on the **Navigation** tab on the left-hand side of the screen (light blue color indicates it as the active tab). Choose the **Show All** option to display the **Treeview**.



Open the folder location for the document you wish to revise. Locate the document and highlight it. Double-click the listing or click **Actions > View** from the right-hand menus to get to the **Document > View** screen for the document metadata.



You can also search for the document using the **Views** tab on the left-hand side in the **DOCUMENT Section**, or use the Search field at the top of the page.



Once you have located your document, double-click the listing or click on the **View** option to open the **Document > View** screen. The document must be in **Approved & Effective** status in order for you to initiate a Retire Cycle.

On the right-hand **Document Workflow** menu, choose **Retire**.

Document > View Expander Kit Assembly

Visibility: Visible

Document File

Device Master Record.docx(9 KB)

Open Get Unmarked PDF Get Editable File Format

Change Summary:

Compare-1.5-1.0_f303046b-9f2f-48df-84d2-1a92ad8ff892.pdf (26 KB)

Open

Standard Attributes

Document Type: Device Master Record

Name: Expander Kit Assembly

Description: <empty>

Unique ID: f303046b-9f2f-48df-84d2-1a92ad8ff892 **Internal Version:** 2.0

Version: 2.0

Control Number: DMR-003

Effective Date: 16-Apr-2018 **Next Review Date:** 16-Apr-2019

Document Life Cycle:

Life Cycle (in months): 12

Planned Review Task Duration (in months) : 2

Document Actions

- View
- Modify
- Modify Metadata Only
- Change Location
- Metadata to PDF
- Clear PDF
- Hide Document
- Get Link
- Email Link

Document Workflow

- Retire

Related Items

- Referred Document
- Reason for Change
- Modify Description
- Remove Links

Related Information

- Audit Trail

The **Document > Retire** screen appears.

Document > Retire

This action does not start the retire cycle. It will create a version To Retire in which the retire cycle can be started.

Visibility: Visible

Not Logged in Audit Trail

Standard Attributes

Document Type: Device Master Record

Name: Expander Kit Assembly

Unique ID: f303046b-9f2f-48df-84d2-1a92ad8ff892

Version: 2.0

Control Number: DMR-003

Confirm Cancel

Document Actions

- View
- Modify
- Modify Metadata Only
- Change Location
- Metadata to PDF
- Clear PDF
- Hide Document
- Get Link
- Email Link

Document Workflow

- Retire

Related Items

- Referred Document
- Reason for Change

This screen displays a Note in a Yellow-shaded area that reads **“This action does not start the retire cycle. It will create a version To Retire in which the retire cycle can be started.”** This is a new Internal Version that will be used to circulate the Approved & Effective version for approval of retirement.

Click the **Confirm** button to get to the next screen.

Note the following on this **Document > Main Page > Modify** screen:

- The **To Retire** tab is active.
- The document **Version** field is not enabled and displays the same version as the Approved & Effective document.
- The **Internal Version** field is not enabled and displays the next internal version.
- The right-hand **Document Workflow** menu includes a **Start Retire Cycle** option.
- The right-hand **Related Information** menu includes a **Retiring History** option.

Authoring
Pending Review
Pending Approval
Pending Retire
Approved, Not Effective
Approved & Effective
To Retire

Document > Main Page > Modify

Visibility: Visible

Document File

Please refer to the appropriate Approved tab to access the document file.

Standard Attributes

Document Type:

* Name:

Description:

Unique ID:

Internal Version:

Version:

Control Number:

Document Actions

View

Modify Metadata Only

Change Location

Cancel in Process

Metadata to PDF

Clear PDF

Get Link

Email Link

Document Workflow

Set Workflow

Start Retire Cycle

Related Items

Referred Document

Reason for Change

Modify Description

Remove Links

Related Information

Audit Trail

Retiring History

Reason for Change:

The **Reason for Change** field will still be enabled and can be used to include a reason for the document Retirement if appropriate.

Click **Submit** and then **Confirm** to save any changes to this or any other fields.

Choose **Document Workflow > Set Workflow** from the right-hand menus. As with the document Revision process, you will be then be able to select people for the Workflow – in this case to approve the Retire Cycle for the document. You can choose from available **Document Workflow Templates** or add people individually. See higher level documents on the SOLABS QM10 DOCUMENT Section for specific details on using these fields.

Workflow Details

Available Templates:

Workflow Parameters

* Cycle Type:

Review
Approval
Retire

Custom Selection

Originator (Author)

Document Owner

* Role:

* User:

Order:
1 Insert

+ADD

Once the people are selected for the **Retire Cycle**, click the **Submit** and then **Confirm**.

Retire Cycle (Serial/Parallel)

Reference Date

Order	Approver (Role)	Approver (User)	Delay (days)	
1	FCT_Manager Supply Chain	kallen (Kelly Allen)	N/A	Remove
1	FCT_Director Manufacturing	cjeanes (Conrad Jeanes)	N/A	Remove
1	FCT_Director Regulatory Affairs	cdunn (Corrina Dunn)	N/A	Remove

Submit **Cancel**

The last step is to select **Start Retire Cycle** from the right-hand Document Workflow menu and then **Confirm**.

Document Workflow

Change Workflow

Start Retire Cycle

The selected people will receive a Notification and be able to approve the Retirement of the document.

The Status tab will now show **Pending Retire**.

Authoring Pending Review Pending Approval **Pending Retire** Approved, Not Effective Approved & Effective Retired

When the last person has completed their approval of the document retirement, they will get the following message (unless they are an Administrator).

Authoring Pending Review Pending Approval Pending Retire Approved, Not Effective Approved & Effective Retired

Document has been successfully retired but you do not have sufficient privileges to access this document.

Views Navigation

Show All
Show All (including hidden, superseded and retired)

Recent Items **Expand**

F: Device Master Records ✖

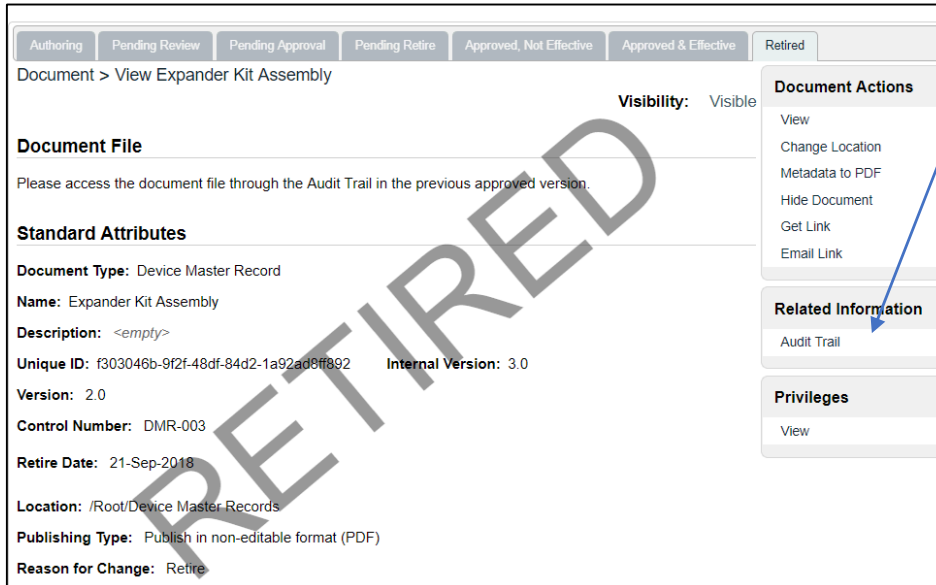
Document > Folders > View

Treewiew

- Root
 - Annual Product Reviews
 - Audit Reports
 - Calibration and Maintenance
 - Clinical Documents
 - Device Master Records**
 - DMR-001 / 1.0 (1.0) / Sterile Vials - [Approved & Effective]
 - DMR-002 / 1.0 (1.0) / IV Set 10-PK - [Approved & Effective]
 - DMR-002 / 2.0 (1.3) / IV Set 10-PK - [Pending Approval]
 - DMR-003 / 2.0 (3.0) / Expander Kit Assembly - [Retired]

SOLABS System Administrators and SOLABS Document Administrators can use the **Show All (including hidden, superseded and retired)** option on the Navigation tab and will now see retired documents listed in Red.

When an Administrator chooses the **View** option for the Retired document, the screen will include a RETIRED watermark – another visual indicator. In the **Document File** section, it is stated that the file can be accessed through the Audit Trail in the previous approved version.



Document > View Expander Kit Assembly

Visibility: Visible

Document File

Please access the document file through the Audit Trail in the previous approved version.

Standard Attributes

Document Type: Device Master Record
Name: Expander Kit Assembly
Description: <empty>
Unique ID: f303046b-9f2f-48df-84d2-1a92ad8ff892 **Internal Version:** 3.0
Version: 2.0
Control Number: DMR-003
Retire Date: 21-Sep-2018
Location: /Root/Device Master Records
Publishing Type: Publish in non-editable format (PDF)
Reason for Change: Retire

Document Actions

- View
- Change Location
- Metadata to PDF
- Hide Document
- Get Link
- Email Link

Related Information

- Audit Trail

Privileges

- View

The **Audit Trail** for the document will provide details and access to the Editable File Content of previous versions of the document should they be needed in the future.

This can be helpful to answer any historical questions or to create a new document - under a different document Name/Control Number - if a retired document needs to become active again in the future.

Access the Audit Trail using the right-hand menu. Expand the Audit Trail for the last Effective version. SOLABS Document Administrators can open both the document file and the compare file. They also still have the options to Get Unmarked PDF and Get Editable File Format.

Document > Expander Kit Assembly > Audit Trail



Expander Kit Assembly

Internal Version: 3.0
Action Details: Document Retired
Date: 21-Sep-2018 16:00:32 UTC-04:00
Username (Full Name): gdixson (Gretchen Dixson)
Reason for Change: N/A

Internal Version: 2.0
Action Details: Modify Metadata Only and Set Effective
Date: 16-Apr-2018 12:24:19 UTC-04:00
Username (Full Name): jclark (Jaqueline Clark)
Reason for Change: Modify metadata - effective date

Document File

File: Device Master Record.docx (9 KB)  [Open](#) | [Get Unmarked PDF](#) | [Get Editable File Format](#)

Change Summary: Compare-1.5-1.0_f303046b-9f2f-48df-84d2-1a92ad8ff892.pdf (26 KB)  [Open](#)